

**REMARKS*****Summary of the Response***

Upon consideration of the remarks presented in the instant response, claims 1 – 23 currently remain pending.

***Summary of the Official Action***

In the instant Office Action, the Examiner has rejected claims 1 – 23 over the art of record. By the present remarks, Applicants submit the rejections have been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the present application.

***Traversal of Rejection Under 35 U.S.C. § 102(b)*****1. Over Webb**

Applicants traverse the rejection of claims 1 – 9, 11, and 18 – 20 under 35 U.S.C. § 102(e) as being anticipated by WEBB et al. (U.S. Patent No. 6,629,533) [hereinafter “WEBB”]. The Examiner asserts WEBB shows all of the claimed features, and that the anchoring arms would be equivalent to the recited pins. Applicants traverse the Examiner’s assertions.

Applicants independent claim 1 recites, *inter alia*, a substantially cylindrical body having an external lateral wall, and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain said lachrymal plug in position. Applicants’ independent claim 19 recites, *inter alia*, positioning in a lachrymal duct a substantially cylindrical body having external lateral wall and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain the

lachrymal plug. Applicants submit that WEBB fails to show at least the above-noted features.

WEBB shows a punctum plug having a circumferentially radiating flexible anchoring arm to secure the plug in the punctum of the wearer. Moreover, WEBB's punctum plug has a large head to provide external support when the plug is secured in the punctum, whereas the present invention is a lachrymal plug positionable within the canicular duct.

A review of WEBB reveals that, while disclosing an anchoring arm that can fold to accommodate narrow punctal openings, WEBB fails to disclose this anchor arm is *structured and arranged to straighten out when positioned to maintain the plug in position*, as recited in at least independent claims 1 and 19. In fact, as WEBB expressly discloses that a portion of the anchoring arm should extend a distance greater than the width of the head, Applicants submit that WEBB provides no teaching of such an anchoring arm straightening out when positioned, as recited in the pending claims.

Because WEBB fails to show at least the above-noted features, Applicants submit that the applied art fails to disclose each and every recited feature of the claims. Therefore, Applicants submit that the applied art fails to provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. § 102(e), and that the present rejection is improper and should be withdrawn.

Further, Applicants note that, as WEBB merely discloses the use of a circumferentially radiating securing arm, the Examiner's assertions that the arm is equivalent to radial pins is based upon no specific teaching in WEBB, but is

based solely upon Applicants' own disclosure. Therefore, Applicants submit, when considered solely upon its own disclosure, WEBB cannot even arguably anticipate the radial pins recited in claims 2 and 20, the arrangement of the pins recited in claims 3 – 7, an additional disk to ensure impermeability recited in claim 8, the manner in which the pins straighten out recited in claim 9, the specifics of the body recited in claim 11, or the manner in which the flexible elements straighten out recited in claim 18.

Further, in addition to foregoing distinguishing features of the dependent claims, Applicants submit that claims 2 – 9, 11, 18, and 20 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 1 – 9, 11, and 18 – 20 under 35 U.S.C. § 102(e) and indicate that these claims are allowable.

***Traversal of Rejection Under 35 U.S.C. § 103(a)***

1. **Over Webb in view of MacKeen**

Applicants traverse the rejection of claims 10, 15, and 21 under 35 U.S.C. § 103(a) as being unpatentable over WEBB in view of MacKEEN et al. (U.S. Patent No. 4,915,684) [hereinafter “MacKEEN”]. While acknowledging that WEBB fails to show a punctum plug having an axial duct for the passage of tears and a specific insertion tool, the Examiner asserts that MacKEEN shows these features, and asserts it would have been obvious to modify WEBB to include the same.

Applicants note that MacKEEN shows a device for modulating flow of lachrymal fluid, which includes an arcuate head, a cylinder, and a peripheral member. However, notwithstanding the features the Examiner asserts are disclosed by MacKEEN, Applicants note MacKEEN, like WEBB, fails to teach or suggest the recited flexible elements that are structured and arranged to straighten out to maintain the position of the plug.

Thus, as neither applied document teaches or suggests at least the above-noted features of at least independent claims 1 and 19, Applicants submit that no proper combination of WEBB in view of MacKEEN can even arguably render unpatentable the instant invention. Thus, Applicants submit the pending rejection is improper and should be withdrawn.

Further, Applicants submit it would not have been obvious to modify WEBB to utilize a tool such as disclosed by MacKEEN. In particular, it is noted that, as the punctum plug of WEBB is simply inserted into the wearer's punctum, no special tools are necessary for insertion, such that there appears to be no rationale or motivation to utilize a specific tool, such as taught by MacKEEN, since to do so would only appear to complicate WEBB's insertion procedure.

Because the art of record fails to provide any teaching or suggestion for combining the art of record in the manner asserted by the Examiner, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Further, in addition to foregoing distinguishing features of the dependent claims, Applicants submit that claims 10, 15, and 21 are allowable at least for the

reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 10, 15, and 21 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

2. Over Webb in view of Freeman

Applicants Traverse the rejection of claims 12 and 13 under 35 U.S.C. §103(a) as being unpatentable over WEBB in view of FREEMAN (U.S. Patent No. 3,949,750). The Examiner asserts, while WEBB fails to show the insert is made of metal or shape memory steel, it would have been obvious to modify WEBB to include an insert being made of metal or shape memory steel, as taught by FREEMAN. Applicants traverse the Examiner's assertions.

Applicants note WEBB fails to teach or suggest flexible elements *structured and arranged to straighten out when positioned*. Moreover, this document fails to provide any teaching or suggestion of forming the flexible securing arm from metal.

While FREEMAN discloses a punctum plug formed of metal, FREEMAN fails to provide any teaching or suggestion that the plug and/or any elements of the plug are flexible. Moreover, Applicants submit that FREEMAN fails to provide any teaching or suggestion of flexible elements *structured and arranged to straighten out when positioned* to maintain the position of the plug, as recited in at least independent claim 1.

As neither WEBB nor FREEMAN teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit, as there is no teaching or suggestion in the art of record of forming flexible elements from metal, it would not have been obvious to modify WEBB to be formed from metal, as disclosed by FREEMAN.

Because the art of record fails to provide any teaching or suggestion for combining the art of record in the manner asserted by the Examiner, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Further, Applicants submit that claims 12 and 13 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

3. Over Webb in view of Herrick

Applicants traverse the rejection of claim 14 under 35 U.S.C. §103(a) as being unpatentable over WEBB in view of HERRICK (U.S. Patent No. 5,163,959). The Examiner asserts that, while WEBB fails to show the insert being made of a radio-opaque material that is visible with X-rays, but that it would have been obvious to modify WEBB to include an insert being made of radio-

opaque material, as taught by HERRICK. Applicants traverse the Examiner's assertions.

As noted above, WEBB fails to teach or suggest flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug, as recited in at least independent claim 1.

Further, while HERRICK discloses a canicular implant, there is no teaching or suggestion of flexible elements, and certainly no suggestion of flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug, as recited in at least independent claim 1.

Because neither document teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Moreover, Applicants submit, as WEBB is directed to an externally supported punctum plug and HERRICK is directed to a canicular implant, these elements are structurally designed for specific uses in different places. Because these elements are distinctly designed for distinct purposes and uses, Applicants submit that the art of record fails to provide any teaching or suggestion for combining these teachings in any manner that would render unpatentable the present invention. Accordingly, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Further, Applicants submit that claim 14 is allowable at least for the reason that it depends from an allowable base claim and because it further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claim 14 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

4. Over Webb in view of Seder

Applicants traverse the rejection of claims 16, 17, 22, and 23 under 35 U.S.C. §103(a) as being unpatentable over WEBB in view of SEDER et al. (U.S. Patent No. 4,959,048) [hereinafter "SEDER"]. The Examiner asserts WEBB shows the recited subject matter with the exception of the tool used to implant the plug having jaws, but that it would have been obvious to modify WEBB to include a tool having jaws, as taught by SEDER. Applicants traverse the Examiner's assertions.

As noted above, WEBB fails to disclose flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug.

Further, while SEDER discloses a lacrimal duct occluder, Applicants submit there is no teaching or suggestion of flexible elements, and certainly no suggestion of flexible elements structuring and arranging flexible elements to straighten out when positioned to maintain a position of the plug, as recited in at least independent claims 1 and 19.

Further, Applicants submit it would not have been obvious to modify WEBB to utilize a tool such as disclosed by SEDER. In particular, it is noted that,

as the punctum plug of WEBB is simply inserted into the wearer's punctum, no special tools are necessary for insertion/removal, such that there appears to be no rationale or motivation to utilize a specific tool, such as taught by SEDER, since to do so would only appear to complicate WEBB's insertion/removal procedure.

Because the art of record fails to provide any teaching or suggestion for combining the art of record in the manner asserted by the Examiner, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Because neither document teaches or suggests at least the above-noted feature of at least independent claims 1 and 19, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claims 16, 17, 22, and 23 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 16, 17, 22, and 23 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

***Application is Allowable***

Thus, Applicants respectfully submit that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§

102 and 103, and respectfully request the Examiner to indicate allowance of each and every pending claim of the present invention.

***Authorization to Charge Deposit Account***

The undersigned authorizes the charging of any necessary fees, including any extensions of time fees required to place the application in condition for allowance by Examiner's Amendment, to Deposit Account No. 19 - 0089 in order to maintain pendency of this application.

**CONCLUSION**

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious the Applicants' invention, as recited in each of claims 1 – 23. The claims have been amended to eliminate any arguable basis for rejection. In addition, the applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,  
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